



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9104-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—

April through June 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2017, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis, JD	(410) 786-8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

SUPPLEMENTARY INFORMATION

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified

providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

Dated: July 20, 2017

Kathleen Cantwell

Director,

Office of Strategic Operations and

Regulatory Affairs.

BILLING CODE 4120-01-P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 5, 2016 (81 FR 51901), November 2016 (81 FR 79489, February 23, 2017 (82 FR 11456), and May 5, 2017 (82 FR 21241). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2017)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have

arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) use (CMS-Pub. 100-03) Transmittal No. 196.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
104	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 October 2017 Updates
105	Update to General Information, Eligibility, and Entitlement, Chapter 7 – Contract Administrative Requirements, Section 40 – Shared System Maintainer Responsibilities for Systems Releases
Medicare Benefit Policy (CMS-Pub. 100-02)	
235	Removal of Contractor Requirement to Submit Opt Out Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 8)
Medicare National Coverage Determination (CMS-Pub. 100-03)	
195	Screening for Hepatitis B Virus (HBV) Infection
196	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
197	Screening for Hepatitis B Virus (HBV) Infection
Medicare Claims Processing (CMS-Pub. 100-04)	
3744	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3745	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3746	July 2017 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3747	Payment for Moderate Sedation Services
3748	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.2, Effective July 1, 2017
3749	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3750	New Fields in the Fiscal Intermediary Shared System (FISS) Inpatient and Outpatient Provider Specific Files (PSF)
3751	Two New “K” Codes for Therapeutic Continuous Glucose Monitors
3752	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3753	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3754	Implementation of New Influenza Virus Vaccine Code Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus and Their Administration on Institutional Claims Payment Procedures for Renal Dialysis Facilities (RDF) CWF Edits on AB MAC (A) Claims CWF Edits on AB MAC (B) Claims CWF Crossover Edits for AB MAC (B) Claims
3755	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3756	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3757	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3758	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3759	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3760	July Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3761	Screening for Hepatitis B Virus (HBV) Infection Screening for Hepatitis B Virus (HBV) Institutional Billing Requirements Professional Billing Requirements Diagnosis Code Reporting Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Messages
3762	New Physician Specialty Code for Advanced Heart Failure and Transplant Cardiology, Medical Toxicology, and Hematopoietic Cell Transplantation and Cellular Therapy Physician Specialty Codes
3763	Table of Preventive and Screening Services Deductible and Coinsurance

3764	Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System
3765	Modifications to the Common Working File (CWF) In Support of the Coordination of Benefits Agreement (COBA) Crossover Process Claims Crossover Disposition and Coordination of Benefits Agreement By-Pass Indicators
3766	Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs)
3767	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3768	April Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3769	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3770	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3771	New Waived Tests
3772	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2017 Update
3773	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3774	Changes to the Payment Policies for Reciprocal Billing Arrangements and Fee-For-Time Compensation Arrangements (formerly referred to as Locum Exceptions to Assignment of Provider’s Right to Payment)-Claims Submitted to A/B MACs Part B Payment Under Reciprocal Billing Arrangements - Claims Submitted to A/B MACs Part B Payment Under Fee-For-Time Compensation Arrangements (formerly referred to as Locum Tenens Arrangements) - Claims Submitted to A/B MACs Part B Billing Procedures for Entities Qualified to Receive Payment on Basis of Reassignment - for A/B MAC Part B Processed Claims Correcting Unacceptable Payment Arrangements Tenens Arrangements)
3775	Two New “K” Codes for Therapeutic Continuous Glucose Monitors
3776	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
3777	July 2017 Integrated Outpatient Code Editor (I/OCE) Specifications Version 18.2
3778	Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes

	(CARCs)
3779	Instructions to Process Services Not Authorized by the Veterans Administration (VA) in a Non-VA Facility Reported With Value Code (VC) 42 Requirements for Processing Non Veterans Administration (VA) Authorized Inpatient Claims
3780	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3781	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule – Update from Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)
3782	Claim Status Category and Claim Status Codes Update
3783	July 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3784	Instructions for Downloading the Medicare ZIP Code File for October Files
3785	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3786	Common Edits and Enhancements Modules (CEM) Code Set Update
3787	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3788	July 2017 Update of the Ambulatory Surgical Center (ASC) Payment System
3789	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3790	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3791	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3792	July 2017 Update of the Ambulatory Surgical Center (ASC) Payment System
3793	Screening for Hepatitis B Virus (HBV) Infection Screening for Hepatitis B Virus (HBV) Institutional Billing Requirements Professional Billing Requirements Diagnosis Code Reporting Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
Medicare Secondary Payer (CMS-Pub. 100-05)	
119	Implement the International Classification of Diseases, Tenth Revision (ICD-10) 2018 General Equivalence Mappings (GEMs) Tables in the Common Working File (CWF) for Purposes of Processing Non-Group Health Plan (NGHP) Medicare Secondary Payer (MSP) Records and Claims
Medicare Financial Management (CMS-Pub. 100-06)	
282	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Qtr Notification for FY 2017
283	New Physician Specialty Code for Advanced Heart Failure and Transplant Cardiology, Medical Toxicology, and Hematopoietic Cell Transplantation and

	Cellular Therapy
Medicare State Operations Manual (CMS-Pub. 100-07)	
169	New to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types
Medicare Program Integrity (CMS-Pub. 100-08)	
710	Update to Pub. 100-08, Chapter 15 Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Approval Letter Guidance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments
711	Update to Pub. 100-08, Chapter 15 Diabetes Self-Management Training (DSMT) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Approval Letter Guidance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments
712	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
713	Scribe Services Signature Requirements
714	Comprehensive Error Rate Testing (CERT) File Layout for Social Security Number Removal Initiative (SSNRI)
715	Update to Pub. 100-08, Chapter 15 Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information
716	Clarifying Medical Review of Hospital Claims for Part A Payment Medical Review of Hospital Claims for Part A Payment

	Conducting Patient Status Reviews of Claims for Medicare Part A Payment for Inpatient Hospital Admissions
717	Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-855I Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments
718	Reviewing for Adverse Legal Actions (ALA)
719	Update to Reporting Requirements Reconsideration Requests – Non-certified Providers/Suppliers External Reporting Requirements
720	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
721	Elimination of Routine Reviews Including Documentation Compliance Reviews and Instituting Three Medical Reviews Overview of Prepayment and Postpayment Reviews Provider Notice Requesting Additional Documentation During Prepayment and Postpayment Review Third-party Additional Documentation Request Special Provisions for Lab Additional Documentation Requests No Response or Insufficient Response to Additional Documentation Requests Reopening Claims with Additional Information or Denied due to Late or No Submission of Requested Information Use of Claims History Information in Claim Payment Determinations Types of Review: Medical Record Review, Non-Medical Record Review, and Automated Review Complex Medical Review Non-Complex Review Automated Review Electronic and Paper Claims Prepayment Review of Claims Involving Utilization Parameters Prepayment Medical Record Review Edits Postpayment Medical Record Review of Claims Re-opening Claims Case Selection CMS Mandated Edits Tracking Medicare Contractors' Postpayment Reviews Denial Types Beneficiary Notification Notifying the Provider Corrective Actions

	Evaluation of Prepayment Edits Suppression and/or Exclusion – Examples Workload Medical Review of Home Health Demand Bills Referrals to the Quality Improvement Organization (QIO) Medical Review Definitions Definition Automated Medical Review Non-Medical Record Review Automated Medical Review Non-Medical Record Review Prepay Provider Specific Medical Record Review Prepay Service Specific Medical Record Review Prepay Provider Specific Probe Medical Record Review Prepay Service Specific Probe Medical Record Review Postpay Provider Specific Probe Medical Record Review Postpay Service Specific Probe Medical Record Review Postpay Provider Specific Medical Record Review Postpay Service Specific Medical Record Review Monthly Reporting of Medical Review Savings
722	Clarifying Date and Timing Requirements for Certain Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS)
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
30	QIO Manual Chapter 16 – “Healthcare Quality Improvement Program” Quality Improvement Interventions Developing and Spreading Successful Interventions Documenting and Disseminating Results
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
172	Suppression of G9678 (Oncology Care Model Monthly Enhanced Oncology Services) Claims OCM Beneficiary Medicare Summary Notice
173	Medicare Care Choices Model - Per Beneficiary per Month Payment (PBPM) Implementation (eligibility updates and clarification)
174	Payment of G9678 (Oncology Care Model Monthly Enhanced Oncology Services) Claims for Beneficiaries Receiving Care in an Inpatient Setting
One Time Notification (CMS-Pub. 100-20)	
1815	Common Working File (CWF) to Archive Inactive Part B Consistency Edits
1816	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1817	Enrollment Data Base (EDB) and Common Working File (CWF) Data

	Resync- Analysis and Design
1818	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
1819	Update to Common Working File (CWF) Blood Editing on Medicare Advantage (MA) Enrollees' Inpatient Claims for Indirect Medical Education (IME) Payment
1820	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1821	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1822	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1823	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1824	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1825	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1826	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1827	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1828	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1829	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1830	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1831	Introductory Letters for Suppliers and Providers Related to the Prior Authorization for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items
1832	Update FISS Editing to Include the Admitting Diagnosis Code Field
1833	Implementing the remittance advice messaging for the 20-hour weekly minimum for Partial Hospitalization Program services
1834	Analysis and Design Working Sessions for the Development of a Pre-Payment Common Additional Documentation Request (ADR) Letter
1835	Reason Codes 36233 and 36330 Bypass for Claims Submitted on the 72x Type of Bill for Services Provided to Beneficiaries with Acute Kidney Injury (AKI) and edits related to not separately payable drugs
1836	Analysis Only-Provider Number Validation Update for the Shared Systems Maintainer (SSM)
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2017)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at:
<http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-2Q17QPU.pdf>

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (April through June 2017)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2017)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the

decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Screening for Hepatitis B Virus (HBV) Infection	210.6	197	04/28/2017	09/28/2016
Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis	150.13	196	05/22/21017	12/08/2016

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2017)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more

information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
G170059	BREATHID MCS	04/05/2017
G160267	Revolution Peripheral Atherectomy System	04/05/2017
G170058	Panoramic in ECGi in Patients with Recurrent AF after PV Isolation	04/06/2017
G170060	Fectoscopic Repair of Myelomeningocele (MMC) in Fetuses with Isolated Spina Bifida	04/07/2017
G170027	AquaBeam System Water II Study	04/10/2017
G170064	INDIGO Aspiration System	04/13/2017
G170065	Panoramic ECGi to guide Ablation of Non-Paroxysmal AF: Effect of Ibutilide on AF Source Location and Organization	04/13/2017
G170066	JET-PCB Trial	04/13/2017
G170067	Intramural Needle Ablation for the Treatment of Refractory Ventricular Arrhythmias	04/13/2017
G170068	CardioMEMS HF System	04/14/2017
G170071	Embosphere Microspheres	04/20/2017
G160156	LimFlow System	04/20/2017
G170073	Osia System	04/21/2017
G160257	Princess FILLER Lidocaine	04/26/2017
G170078	Avenger's Pantheris Atherectomy Catheter	04/27/2017
G170079	NovoTTF-200A (TTFields)	04/30/2017
G160224	Countour PVA, Embosphere and Embozene Particles	05/02/2017
BB17426	CliniMACS TCRalpha-beta/CD19 Combined Depletion System	05/02/2017
G160227	Svelte Sirolimus-Eluting Coronary Stent	05/03/2017
G170085	Guardant360 CDx Test	05/03/2017
G170087	Osia System	05/05/2017
G150110	Emervel Lips	05/05/2017
G170090	Artimes pro Balloon Dilatation Catheter	05/08/2017
G170049	RADAR: Real-time electrogram Analysis for Drivers of Atrial fibrillation	05/09/2017
G170095	RADIESSE (+) Lidocaine 1.5cc	05/11/2017
G170093	A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients	05/12/2017
G170084	gammaCore-R	05/16/2017
BB17455	Cytori Celution System	05/17/2017
G170098	JUVEDERM VOLBELLA XC for Correction of Infraorbital Hollowing	05/18/2017
G160235	BuMA Supreme Biodegradable Drug Coated Coronary Stent System	05/18/2017
G170102	Foundation Medicine Blood First Assay Screening Trial (BFAST) Clinical Trial Assay (CTA)	05/19/2017
G170105	Insulin Pump System with Predictive Low Glucose Suspend	05/26/2017
G170109	SPY Portable Handheld Imaging (SPY-PHI) System (HH9000); IC2000 (Indocyanine Green for Injection, USP)	05/26/2017

IDE	Device	Start Date
G170112	SPY Portable Handheld Imaging (SPY-PHI) System (HH9000); IC2000 (Indocyanine Green for Injection, USP)	05/30/2017
G170114	Micra Atrial TRacking Using A Ventricular AccELerometer (MARVEL) clinical feasibility study	06/01/2017
G170111	MED-EL SYNCRONY Cochlear Implant System	06/02/2017
G170116	RETINA IMPLANT Alpha AMS	06/02/2017
G170118	TVRS Clip Delivery System, TVRS Steerable Guide Catheter	06/02/2017
G170110	Left Atrial Anatomy Reconstruction Using Model Based Fast Anatomical Mapping	06/05/2017
G170120	B-FAST bTMB CTA	06/06/2017
G170119	MAGE-A4 Immunohistochemistry (IHC) Clinical Trial Assay (CTA)	06/07/2017
G170125	myChoice HRD CDx	06/12/2017
G170128	Transdermal Compress	06/14/2017
G170081	XIENCE Apine Everolimus Eluting Coronary Stent System; XIENCE Xpedition Everolimus Eluting Coronary Stent System	06/15/2017
G170127	MagPro MST manufactured by MagVenture, Inc.	06/16/2017
G170129	Apollo System	06/16/2017
G170130	SurgiMed Collagen Matrix	06/16/2017
G170132	Belotero Balance with Integral Lidocaine (Project description)	06/16/2017
G170140	NY-ESO-1 Immunohistochemistry (IHC) Clinical Trial Assay (CTA)	06/21/2017
G170077	Exablate Model 4000 Type-1 system	06/22/2017
G170138	Telsa Magnetic Resonance Research Device	06/23/2017
G170144	Cardiva Mid-Bore Venous Vascular Closure System (VVCS)	06/23/2017
G170016	RxLAL, Light Delivery Device and Rx Sight Insertion Device	06/23/2017
G170139	Cochlear Implantation during Vestibular Schwannoma Removal or during Labyrinthectomy surgery for treatment of Meniere's disease	06/28/2017
G170147	RCstim Model 1114R or 1114L Soft Tissue Stimulator	06/28/2017
BB17524	Treatment of erectile dysfunction (ED)	06/29/2017
G170133	Med-El cochlear implant insertion electrode	06/30/2017
G170146	RestoreSensor SureScan MRI Implantable Neurostimulation System	06/30/2017

Addendum VI: Approval Numbers for Collections of Information (April through June 2017)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2017)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage> For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Parkview Medical Center 400 W. 16th Street Pueblo, CO 81003	060020	04/05/2017	CO
St Francis Xavier Hospital 2095 Henry Tecklenburg Drive Charleston, SC 29414	420065	04/27/2017	SC
Garfield Medical Center 525 N. Garfield Avenue Monterey Park, CA 91754	050737	05/12/2017	CA
Kaiser Foundation Hospital Sacramento 2025 Morse Avenue Sacramento, CA 95825	1952476665	06/30/2017	CA
The following facilities have editorial changes (in bold).			
FROM: Oakwood Hospital and Medical Center TO: Beaumont Hospital – Dearborn 18101 Oakwood Boulevard Dearborn, MI 48123-2500 P.O Box 2500	230020	07/07/2005	MI
FROM: Howard Regional Health System TO: Community Howard Regional Health 3500 South Lafountain Street Kokomo, IN 46904-9011 P.O. Box 9011	150007	09/08/2005	IN
FROM: Brackenridge Hospital	450124	06/07/2005	TX

Facility	Provider Number	Effective Date	State
TO: Dell Seton Medical Center at The University of Texas 1500 Red River Street Austin, TX 78701			
The following facilities are terminations for this quarter.			
San Ramon Regional Medical Center 6001 Norris Canyon Road San Ramon, CA 94583	050689	06/07/2005	CA

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2017)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the

American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	City	State
The following facilities are new listings for this quarter.		
Interfaith Medical Center	Brooklyn	NY
Mid-Columbia Medical Center	The Dalles	OR
Midstate Medical Center	Meriden	CT
Olmsted Medical Center	Rochester	MN
UNMH - Sandoval Regional Medical Center	Rio Rancho	NM
Houston Methodist The Woodlands	The Woodlands	TX
Glacial Ridge Hospital District	Glenwood	MN
Promedica Defiance Regional Hospital	Defiance	OH
Alaska Cardiovascular Surgery Center, LLC	Anchorage	AK
Lakeview Hospital	Bountiful	UT
Fort Sutter Surgery Center, L.P.	Sacramento	CA
Holy Cross Germantown Hospital	Germantown	MD
Ellwood City Hospital	Ellwood City	PA
Marshfield Clinic - Wausau Center	Marshfield	WI

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2017)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

**Addendum X:
List of Special One-Time Notices Regarding National Coverage
Provisions (April through June 2017)**

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

**Addendum XI: National Oncologic PET Registry (NOPR)
(April through June 2017)**

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

**Addendum XII: Medicare-Approved Ventricular Assist Device
(Destination Therapy) Facilities (April through June 2017)**

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet

our standards in order to receive coverage for VADs implanted as destination therapy.

There were no additions, deletions, or editorial changes to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact Linda Gousis, JD, (410-786-8616).

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(April through June 2017)**

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities
(April through June 2017)**

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI)

greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at [FR Doc. 2017-16252 Filed: 8/3/2017 8:45 am; Publication Date: 8/4/2017]

www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2017)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).